

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1.– 74. (cancelled)

75. (new) A pharmaceutical dosage form which comprises (a) a first drug which is at least one of promethazine and a pharmaceutically acceptable salt thereof and (b) at least one second drug, wherein a plasma half-life of the at least one second drug is shorter than a plasma half-life of the first drug by at least about 3 hours and the dosage form provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 70 % of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug.

76. (new) The dosage form of claim 75, wherein the plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 4 hours.

77. (new) The dosage form of claim 75, wherein the plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 6 hours.

78. (new) The dosage form of claim 75, wherein the period of a plasma concentration within

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the therapeutic range of the at least one second drug is coextensive with at least about 80 % of the period of a plasma concentration within the therapeutic range of the first drug.

79. (new) The dosage form of claim 76, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 90 % of the period of a plasma concentration within the therapeutic range of the first drug.

80. (new) The dosage form of claim 75, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 95 % of the period of a plasma concentration within the therapeutic range of the first drug.

81. (new) The dosage form of claim 75, wherein the first drug comprises promethazine hydrochloride.

82. (new) The dosage form of claim 75, wherein the at least one second drug comprises an antitussive.

83. (new) The dosage form of claim 82, wherein the antitussive comprises at least one of codeine and a pharmaceutically acceptable salt thereof.

84. (new) The dosage form of claim 82, wherein the antitussive comprises at least one of

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dihydrocodeine and a pharmaceutically acceptable salt thereof.

85. (new) The dosage form of claim 82, wherein the antitussive comprises at least one of hydrocodone and a pharmaceutically acceptable salt thereof.

86. (new) The dosage form of claim 82, wherein the antitussive comprises at least one of dextromethorphan and a pharmaceutically acceptable salt thereof.

87. (new) The dosage form of claim 75, wherein the at least one second drug comprises a decongestant.

88. (new) The dosage form of claim 87, wherein the second drug comprises at least one of phenylephrine and a pharmaceutically acceptable salt thereof.

89. (new) The dosage form of claim 87, wherein the second drug comprises at least one of pseudoephedrine and a pharmaceutically acceptable salts thereof.

90. (new) The dosage form of claim 75, wherein the at least one second drug comprises an antihistamine.

91. (new) The dosage form of claim 90, wherein the antihistamine comprises at least one of

chlorpheniramine and a pharmaceutically acceptable salt thereof.

92. (new) The dosage form of claim 75, wherein the at least one second drug comprises an expectorant.

93. (new) The dosage form of claim 92, wherein the expectorant comprises guaifenesin.

94. (new) The dosage form of claim 75, wherein the dosage form comprises a tablet.

95. (new) The dosage form of claim 94, wherein the tablet has at least two layers.

96. (new) The dosage form of claim 95, wherein the tablet is a bi-layered tablet.

97. (new) The dosage form of claim 94, wherein the tablet comprises a matrix which comprises the first drug and has dispersed therein particles which comprise the at least one second drug.

98. (new) The dosage form of claim 97, wherein the matrix has dispersed therein particles which comprise a second drug and a third drug.

99. (new) The dosage form of claim 97, wherein the matrix has dispersed therein particles which comprise a second drug, a third drug and a fourth drug.

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100. (new) The dosage form of claim 97, wherein the matrix provides an immediate release of the first drug and the particles provide a controlled release of the at least one second drug.

101. (new) A tablet which comprises (a) a first drug which is at least one of promethazine and a pharmaceutically acceptable salt thereof and (b) at least one second drug selected from antitussives, decongestants, expectorants, mucus thinning drugs, analgesics and antihistamines, wherein a plasma half-life of the at least one second drug is shorter than a plasma half-life of the first drug by at least about 4 hours and the dosage form provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 80 % of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug.

102. (new) The tablet of claim 101, wherein the at least one second drug comprises a decongestant and a plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 6 hours.

103. (new) The tablet of claim 102, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 90 % of the period of a plasma concentration within the therapeutic range of the first drug.

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104. (new) A bi-layered tablet which comprises a first layer and a second layer, the first layer comprising a first drug which is at least one of promethazine and a pharmaceutically acceptable salt thereof, and the second layer comprising at least one second drug, wherein a plasma half-life of the at least one second drug is shorter than a plasma half-life of the first drug by at least about 3 hours and the bi-layered tablet provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 80% of a period over which the bi-layered tablet provides a plasma concentration within a therapeutic range of the first drug.

105. (new) The bi-layered tablet of claim 104, wherein the plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 4 hours.

106. (new) The bi-layered tablet of claim 104, wherein the plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 6 hours.

107. (new) The bi-layered tablet of claim 104, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 90 % of the period of a plasma concentration within the therapeutic range of the first drug.

108. (new) The bi-layered tablet of claim 105, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 95 % of the period of a plasma concentration within the therapeutic range of the first drug.

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109. (new) The bi-layered tablet of claim 104, wherein the at least one second drug comprises at least one drug selected from decongestants, antitussives, expectorants, mucus thinning drugs, analgesics, and antihistamines.

110. (new) The bi-layered tablet of claim 104, wherein the second layer comprises at least one of phenylephrine and a pharmaceutically acceptable salt thereof.

111. (new) The bi-layered tablet of claim 104, wherein the second layer comprises at least one of pseudoephedrine and a pharmaceutically acceptable salt thereof.

112. (new) The bi-layered tablet of claim 104, wherein the second layer comprises at least one of chlorpheniramine and a pharmaceutically acceptable salt thereof.

113. (new) The bi-layered tablet of claim 104, wherein the first layer comprises promethazine hydrochloride and the second layer comprises at least two of phenylephrine, pseudoephedrine, and chlorpheniramine, including pharmaceutically acceptable salts thereof.

114. (new) The bi-layered tablet of claim 104, wherein the first layer comprises only promethazine or a pharmaceutically acceptable salt thereof as an active ingredient.

115. (new) The bi-layered tablet of claim 105, wherein the first layer comprises only

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promethazine hydrochloride as an active ingredient.

116. (new) The bi-layered tablet of claim 104, wherein the first layer is an immediate release layer.

117. (new) The bi-layered tablet of claim 116, wherein the second layer is a controlled release layer.

118. (new) The bi-layered tablet of claim 117, wherein the second layer is a sustained release layer.

119. (new) The bi-layered tablet of claim 104, wherein the first layer contains from about 0.1 mg to about 90 mg of promethazine hydrochloride.

120. (new) The bi-layered tablet of claim 114, wherein the first layer is an immediate release layer that contains from about 25 mg to about 50 mg of promethazine hydrochloride.

121. (new) The bi-layered tablet of claim 120, wherein the second layer is a sustained release layer and contains from about 0.1 mg to about 16 mg of chlorpheniramine maleate or an equivalent amount of at least one other pharmaceutically acceptable salt of chlorpheniramine.

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122. (new) The bi-layered tablet of claim 120, wherein the second layer is a sustained release layer and contains from about 1 mg to about 90 mg of phenylephrine hydrochloride or an equivalent amount of at least one other pharmaceutically acceptable salt of phenylephrine.

123. (new) The bi-layered tablet of claim 120, wherein the second layer is a sustained release layer and contains from about 1 mg to about 240 mg of pseudoephedrine hydrochloride or an equivalent amount of at least one other pharmaceutically acceptable salt of pseudoephedrine.

124. (new) The bi-layered tablet of claim 121, wherein the second layer comprises at least one excipient selected from cellulose esters, polymers based on vinylacetate, and polymers and copolymers of at least one of methacrylic acid and a methacrylate.

125. (new) The bi-layered tablet of claim 122, wherein the second layer comprises at least one of excipient selected from cellulose esters, polymers based on vinylacetate, and polymers and copolymers of at least one of methacrylic acid and a methacrylate.

126. (new) The bi-layered tablet of claim 123, wherein the second layer comprises at least one of excipient selected from cellulose esters, polymers based on vinylacetate, and polymers and copolymers of at least one of methacrylic acid and a methacrylate.

127. (new) A bi-layered tablet which comprises a first layer and a second layer, the first layer

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comprising as the only active ingredient thereof a first drug which is at least one of promethazine and a pharmaceutically acceptable salt thereof, and the second layer comprising at least one second drug which is selected from decongestants, antitussives, expectorants, mucus thinning drugs, and antihistamines, wherein a plasma half-life of the at least one second drug is shorter than a plasma half-life of the first drug by at least about 4 hours and the bi-layered tablet provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 90% of a period over which the bi-layered tablet provides a plasma concentration within a therapeutic range of the first drug.

128. (new) The bi-layered tablet of claim 127, wherein the plasma half-life of the at least one second drug is shorter than the plasma half-life of the first drug by at least about 6 hours.

129. (new) The bi-layered tablet of claim 127, wherein the first layer is an immediate release layer.

130. (new) The bi-layered tablet of claim 129, wherein the second layer is a sustained release layer.

131. (new) The bi-layered tablet of claim 130, wherein the first layer contains from about 0.1 mg to about 90 mg of promethazine hydrochloride.

132. (new) The bi-layered tablet of claim 131, wherein the first layer contains from about 25 mg to about 50 mg of promethazine hydrochloride.

133. (new) The bi-layered tablet of claim 127, wherein the second layer comprises at least one excipient selected from cellulose esters, polymers based on vinylacetate, and polymers and copolymers of at least one of methacrylic acid and a methacrylate.

134. (new) A pharmaceutical dosage form which comprises (a) a first drug which is an antihistamine and has a first plasma half-life and (b) at least one second drug which is selected from decongestants, antitussives, expectorants, mucus thinning drugs, analgesics, and antihistamines and has a second plasma half-life which differs from the first plasma half-life by at least about 3 hours, wherein the dosage form provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 70 % of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug.

135. (new) The dosage form of claim 134, wherein the first plasma half-life is longer by at least about 4 hours than the plasma half-life of the at least one second drug.

136. (new) The dosage form of claim 134, wherein the first plasma half-life is longer by at least about 6 hours than the plasma half-life of the at least one second drug.

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137. (new) The dosage form of claim 135, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 80 % of the period over which the dosage form provides a plasma concentration within the therapeutic range of the first drug.

138. (new) The dosage form of claim 135, wherein the period of a plasma concentration within the therapeutic range of the at least one second drug is coextensive with at least about 95 % of the period over which the dosage form provides a plasma concentration within the therapeutic range of the first drug.

139. (new) The dosage form of claim 134, wherein the dosage form comprises a bi-layered tablet.

140. (new) The dosage form of claim 135, wherein the first plasma half-life is at least about 8 hours.

141. (new) The dosage form of claim 134, wherein the at least one second drug comprises a decongestant.

142. (new) The dosage form of claim 134, wherein the at least one second drug comprises an antitussive.

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143. (new) The dosage form of claim 134, wherein the at least one second drug comprises an expectorant.

144. (new) The dosage form of claim 134, wherein the at least one second drug comprises a mucus thinning drug.

145. (new) The dosage form of claim 134, wherein the at least one second drug comprises an antihistamine.

146. (new) The dosage form of claim 134, wherein the at least one second drug comprises an analgesic.